Orthos
ORTHOBIOLOGICS

OCT 26 2006

K062260

510(k) Summary of Safety and Effectiveness

In accordance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the subject device.

Orthos Limited
The Stables, Leigh Court,
Abbots Leigh, Bristol,
BS8 3RA, UK.

T: +44 (0) 1275 376 377
F: +44 (0) 1275 376 378

E: info@orthos.com
www.orthos.com

Submitted By:	Orthos Limited
Date:	July 2006
Contact Person:	Alan Rorke Managing Director
Proprietary Name:	Orthos-BMA Kit
Common Name:	Piston Syringe
Classification Name and Reference:	Piston Syringe - 21 CFR 880.5860
Device Product Code:	FMF

DEVICE INFORMATION

A. Device Description

The Orthos-BMA™ kit contains the apparatus required for the collection of bone marrow using a minimally invasive aspiration technique.

The Orthos-BMA™ kit provides the surgeon with a convenient method of harvesting autologus bone marrow and combining it with their choice of osteoconductive material such as autogenous bone or a bone void filler such as ßGran synthetic osteoconductive scaffold.

The Orthos-BMA kit is supplied sterile for single patient use.

B. Intended Use and indications

The Orthos-BMA™ kit is intended for use by suitable trained surgical personnel only.

The Orthos-BMA™ kit contains the apparatus required to harvest bone marrow and to combine the harvested marrow cells with an osteoconductive material such as a bone void filler for use in the treatment of osseous defects, which can occur as a result of trauma, or in skeletal defects created surgically.

C. Substantial Equivalence Rationale

The intended use, the materials and design features employed in the Orthos-BMA™ kit are equivalent to those found in the predicate devices previously cleared for market as described in the pre-market notification. The safety and effectiveness of the Orthos-BMA kit are adequately supported by the data provided within the Pre-market Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2006

Orthos Limited
% Mr. Alan Rorke
Managing Director
The Sables, Leigh Court
Abbots Leights, Bristol
BS8 3RA, UK

Re: K062260
Trade/Device Name: The Orthos-BMA™ kit
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: October 10, 2006
Received: October 13, 2006

Dear Mr. Rorke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K062260

Device Name: Orthos-BMA™ Kit

Indications for Use:

The Orthos-BMA™ kit is intended for use by suitable trained surgical personnel only.

The Orthos-BMA™ kit contains the apparatus required to harvest bone marrow and to combine the harvested marrow cells with an osteoconductive material such as a bone void filler for use in the treatment of osseous defects which can occur as a result of trauma or in skeletal defects created surgically.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)
X		

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General [illegible]rative,
and Neurological D[illegible]ces

510(k) Number K062260